FDA 510(k) Premarket Notification

K182140 da Vinci Xi Surgical System, da Vinci X Surgical System

CLEARED

Oct 24, 2018
78 days to decision

K182140 · Product code: **NAY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k182140/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Surgical, Computer Controlled Instrument (NAY)
Date received	Aug 7, 2018
Decision date	Oct 24, 2018
Days to decision	78 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Intuitive Surgical, Inc.**
Location	Sunnyvale, CA, US
Contact	Brandon Hansen
Website	https://www.intuitive.com
510(k) history	176 submissions · 156 cleared · 1997-2026

Intuitive Surgical, Inc. is an American biotechnology company headquartered in Sunnyvale that develops and manufactures robotic surgical systems. The company specializes in minimally invasive surgery technologies, most notably the da Vinci Surgical System. Intuitive Surgical has received FDA 510(k) clearances from total submissions since its first clearance in 1997. The company's dominant focus is General & Plastic Surgery devices, which represent 87% of its regulatory submissions. The latest FDA 510(k) clearance was granted in 2026, reflecting continued innovation and ac...

REGULATORY CONSULTANT

Consulting firm	**Domecus Consulting Services, LLC**
Contact	Cindy Domecus

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov